REMARKS

Claims 66-83 are pending in the above-identified patent application. Claims 66 and 74 are amended herein. Claims 75-83 are withdrawn.

1. Restriction

The Examiner required restriction under 35 USC §121 to one of four groups:

Group I. Compounds wherein X represents S, classified in class 548, subclass 315.1;

Group II. Compounds wherein X represents O, classified in class 548, subclass 315.4;

Group III. Compounds wherein X represents N, classified in class 548, subclass 314.7;

Group IV. Claim 74, drawn to a composition containing additional active ingredients, classified in class 514 various subclasses; and

Group V. Claims 75-83, drawn to multiple uses, classified in class 514 various subclasses.

Applicants elect Group III, compounds wherein X is N. This election is made with partial traverse. Applicants do not traverse the restriction of compound claims with regard to Groups I-III. Applicants do traverse the restriction of composition claim 74 (Group IV) and method claims 75-83 (Group V) from the compound claims for the reasons provided below.

For examination purposes, Applicants elect the species represented by the compound of Example 18, 2-[4-(1-isopropylaminocarbonyl-piperidin-4-ylmethyl)-phenyl]amino-imidazoline, on page 80 of Applicants' specification.

Claim 1 has been amended to remove non-elected subject matter, and method claims 75-83 have been withdrawn. Claim 74 has been amended to correct its dependency.

a. Traverse Regarding Group IV

The Applicants respectfully traverse the restriction of composition claim 74 with respect to the product base claim 66. The Examiner's restriction incorrectly characterizes claim 74 as being drawn to a composition "containing additional active ingredients". Claim 74 does not recite a "combination therapy" composition that includes additional active ingredients. Instead, claim 74 recites a simple pharmaceutical composition comprising an effective amount of a compound of base claim 66 "in admixture with at least one pharmaceutically acceptable carrier" (claim 74 is amended herein to correct its dependency from previously canceled claim 1 to base claim 66).

A pharmaceutical carrier is understood by those skilled in the art to be "a usually inactive accessory substance", c.g., "a *carrier* for a drug or an insecticide" (Merriam Webster online Dictionary). Applicants' specification names numerous well known inert solid carriers on page 44 (magnesium carbonate, magnesium stearate, talc, sugar, lactose, pectin, dextrin, starch, gelatin, tragacanth, methylcellulose, sodium carboxymethylcellulose, low melting wax, cocoa butter) that may be used in the composition of claim 74. No active ingredient other than the compound of base claim 66 is recited in claim 74.

The Examiner, in defining "independent" (MPEP §802.01), stated that "Independent means the compound is capable of being used alone, not in combination with other compounds listed in the Markush expression". The Applicants note that claim 74 does not include any Markush listing, and respectfully believe that the Examiner is in error in this characterization of claim 74 as having such a listing. As related above, claim 74 simply recites a composition comprising a compound of base claim 66 in admixture

with at least one pharmaceutically acceptable carrier. This recitation represents two separate claim elements and does not represent a Markush grouping.

The Applicants also respectfully disagree with the Examiner's definition of "independent" with regard to MPEP §802.01. This section states more specifically:

> "The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, for example: (1) species under a genus which species are not usable together as disclosed; or (2) process and apparatus incapable of being used in practicing the process."

In order to administer a pharmaceutically active compound to a patient or subject in need thereof, some form of carrier will nearly always be required. Applicants are unaware of any pharmaceutical delivery system that does not employ a carrier. Since a carrier is required for a pharmaceutically active compound, Applicants believe that claim for the active compound, and a claim for a composition comprising that compound together with a carrier, are inherently connected in design, operation and effect". In other words, a pharmaceutical composition comprising an active compound and a carrier is not an "independent" invention with respect to the active compound itself.

The Examiner also stated that "Inventions I-III and IV are patentably distinct because inventions I-III do not require an additional active ingredient for patentability".

Applicants again note that claim 74 recites only one active ingredient. The Applicants are confused by the Examiner's characterization of "distinct" with regard to MPEP §802.01. This section states that:

> "The term "distinct" means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use, or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER".

As noted above, a carrier for delivery of a pharmaceutically active compound is generally required, and a pharmaceutically active compound offers no separate uses from the combination of an active compound and an inert carrier.

Further, the formulation of pharmaceutically active compounds with inert carriers is widespread and well known in the art, and it could not reasonably be said that a composition comprising a patentable pharmaceutically active compound and a conventional carrier is patentably distinct from the pharmaceutically active compound itself. If the Applicants (or another party) had previously disclosed (published) a particular IP receptor antagonist useful for treatment of genitourinary indications, would a subsequent claim by Applicants for a composition comprising that same IP receptor antagonist together with a pharmaceutically acceptable carrier be patentable over such a disclosure? The Applicants believe not. Accordingly, the Applicants respectfully believe that the composition represented by claim 74 is not patentably distinct from base claim 66.

b. Traverse Regarding Group V

MPEP § 821.04 provides, inter alia, that:

> "if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined."

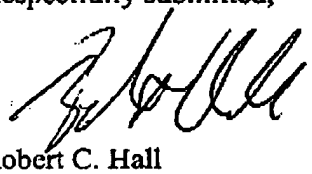
The Applicants respectfully believe that, in the event that base claim 66 is allowed, method claims 75-83, which depend from claim 66, may be rejoined. The Examiner did not mention the possibility of rejoinder, and Applicants respectfully traverse the restriction of Group V from the product claims of Group V if rejoinder is not possible. Applicants note that withdrawn method claim 75 is improperly dependent upon composition claim 74. In the event of rejoinder, this error, for which Applicants apologize, will be corrected by amendment.

CONCLUSION

The Applicants respectfully believe that all claims pending in the above-identified case are now in condition for allowance. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-354-7540.

No fees should be due. However, in the event it is determined that a fee is due, please charge same to Deposit Account No. 18-1700.

Respectfully submitted,



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